510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k042865

B. Purpose for Submission:
Notification of intent to manufacture and market the device: Urine Toxicology Control

C. Measurand:
d-Methamphetamine, 9-COOH-11-nor-Δ9-THC, Benzoylecgonine, Morphine, Phencyclidine, 3,4-Methylenedioxymethamphetamine

D. Type of Test:
Control Material

E. Applicant:
Bio-Rad

F. Proprietary and Established Names:
Proprietary Name – Liquichek Urine Toxicology Control
Established Name – Drug Mixture Control

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.3280 Clinical toxicology control material

2. Classification:
   Class I

3. Product code:
   DIF

4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s): Liquichek Urine Toxicology Control (Levels S1S and S2S) are intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.

2. Indication(s) for use: Liquichek Urine Toxicology Control (Levels S1S and S2S) intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.

3. Special conditions for use statement(s): For prescription use only.

4. Special instrument requirements: N/A

I. Device Description: Liquichek Urine Toxicology Control (Levels S1S and S2S) are intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures. Liquichek Urine Toxicology Control Levels S1S and S2S are prepared from human urine with added drugs of abuse, metabolites of drugs of abuse, preservatives, stabilizers, and constituents of animal origin. The controls are provided as a liquid for convenience.

These controls also contain controls for adulteration (Creatinine, pH, specific gravity). Since assays for these tests are not considered Medical Devices, the adulteration controls were not reviewed.

J. Substantial Equivalence Information:

1. Predicate device name(s): Bio-Rad Liquichek Urine Toxicology Control

2. Predicate 510(k) number(s): k022707

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Liquichek Urine Toxicology Control (Levels S1S and S2S) are intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.	Liquichek Urine Toxicology Control (Levels S1S and S2S) are intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage (unopened)	2 – 8 ^{o}C until expiration date	2 – 8 ^{o}C until expiration date
Open Vial	30 days at 2 – 8 ^{o}C	30 days at 2 – 8 ^{o}C

Differences		
Item	Device	Predicate
Drugs	d-Methamphetamine, 9-COOH-11-nor-Δ9-THC, Benzoylecgonine, Morphine (Free), Phencyclidine, 3,4 – Methylenedioxy-methamphetamine	d-Methamphetamine, 9-COOH-11-nor-Δ9-THC, Benzoylecgonine, Morphine(Free), Phencyclidine, Secobarbital, Lormetazepam, Ethanol, LSD, Methadone, Methaqualone, Nortriptyline Propoxyphene, Tricyclic Antidepressants

K. Standard/Guidance Document Referenced (if applicable): No Standard or Guidance Document was referenced in this submission

L. Test Principle: N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility: N/A

   b. Linearity/assay reportable range: N/A

   c. Traceability, Stability, Expected values (controls, calibrators, or methods): Liquichek Urine Toxicology Control Level S1S contains drugs of abuse and/or metabolites of drugs of abuse added during manufacture at concentrations of 20 – 25% below enzyme immunoassay cutoff levels as recommended by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and other agencies.

   Liquichek Urine Toxicology Control Level S2S contains drugs of abuse and/or metabolites of drugs of abuse added during manufacture at concentrations of 20 – 25% above enzyme immunoassay cutoff levels as recommended by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and other agencies.

   The gravimetric values printed in the package insert represent the amount of drugs of abuse and/or metabolites of drugs of abuse added in the manufacture

of the product. The product has been tested by immunoassay and gas chromatography (GC) to confirm the recovery of quantities added.

Open vial stability - All analytes will be stable for 30 days at 2-8 ^{o}C. T_{zero} support the 30 days open vial claim, these products were stored at 2-8 ^{o}C and tested for 36 days (T_{final}), which is 20% longer than the claim. On the last day (T_{final}), recovery results were compared against freshly opened vials (T_{zero}) by GC/MS method. The acceptance criteria were defined as the recovery of T_{final} being within ± 10% of the T_{zero} values.

Shelf life stability - Accelerated stability – These studies were performed at elevated temperatures to observe changes in product performance more rapidly than would be seen under normal storage conditions of 2-8 ^{o}C. The products were tested at three elevated temperatures and the shelf stability was predicted using a stability model with activation energy of 20-kCal/mole.

Shelf life stability – Real time closed vial stability – The product's stability will be verified by storing the product under the recommended storage conditions of 2-8 ^{o}C for the life of the product plus 10%. These are long-term studies and are on-going.

d. Detection limit: N/A

e. Analytical specificity: N/A

f. Assay cut-off: N/A

2. Comparison studies:
   a. Method comparison with predicate device: N/A

   b. Matrix comparison: N/A

3. Clinical studies:
   a. Clinical Sensitivity: N/A

   b. Clinical specificity: N/A

   c. Other clinical supportive data (when a. and b. are not applicable): N/A

4. Clinical cut-off**:** N/A

5. Expected values/Reference range: N/A

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.